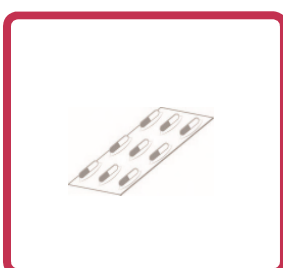
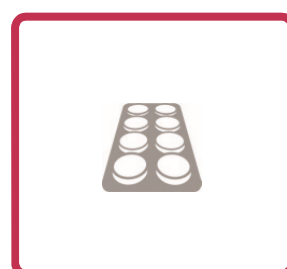
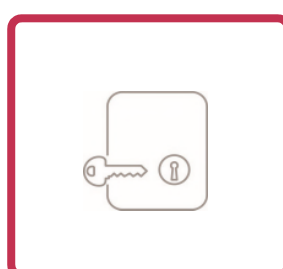


The safer management of controlled drugs

Annual update 2019

Published July 2020



The Care Quality Commission

The Care Quality Commission is the independent regulator of health and adult social care in England.

We make sure that health and social care services provide people with safe, effective, compassionate, high-quality care and we encourage care services to improve.

Our role

- We register health and adult social care providers.
- We monitor and inspect services to see whether they are safe, effective, caring, responsive and well-led, and we publish what we find, including quality ratings.
- We use our legal powers to take action where we identify poor care.
- We speak independently, publishing regional and national views of the major quality issues in health and social care, and encouraging improvement by highlighting good practice.

We also have a statutory duty to oversee the safe management arrangements for controlled drugs in England.

Our values

- Excellence – being a high performing organisation.
- Caring – treating everyone with dignity and respect.
- Integrity – doing the right thing.
- Teamwork – learning from each other to be the best we can.

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Introduction

The Care Quality Commission (CQC) is responsible for making sure that health and adult social care providers, and other regulators, maintain a safe environment for the management and use of controlled drugs in England. We do this under the Controlled Drugs (Supervision of Management and Use) Regulations 2013.

These regulations were amended on 1 April 2020 to the Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations 2020. The amendment removed the 'sunset clause' and included the task of reviewing the regulations within five years.

As part of our responsibilities under the regulations, we report annually on what we find through our oversight. Based on this information, we also make recommendations to help ensure the continuing effectiveness of the arrangements for managing controlled drugs in England.

Our findings are important for:

- all controlled drugs accountable officers (CDAOs) in England and their support teams
- organisations that handle controlled drugs
- health and care professionals with an interest or remit in controlled drugs
- commissioners of healthcare services
- professional healthcare and regulatory bodies.

The data we use in this annual update relates to the calendar year 2019, but we also include relevant information for the first half of 2020 and will cover the period during the COVID-19 outbreak.

In this update, we look at key issues and areas of interest:

- opioid medicines
- Gosport Independent Panel report
- cannabis-based medicinal products
- issues relating to the coronavirus (COVID-19) pandemic.

Recommendations

From our analysis of the data on prescribing in NHS primary care services, feedback from attendance at controlled drug local intelligence networks (CDLINs), and CQC's wider inspection and regulatory work, we make the following recommendations for improvement:

1. The level of controlled drug prescribing continues to increase year on year. Unnecessary prescribing for long-term treatment can result in an accumulation of unwanted medicines in patients' homes, which increases waste and the associated risks of misuse. Furthermore, patients commonly do not fully understand the risk of dependence on long-term treatment with many of the scheduled controlled drugs and the importance of returning them to a community pharmacy once they no longer need them. To address this:
 - **prescribers should regularly review patients' clinical needs before prescribing and consider the quantity prescribed, particularly when issuing repeat prescriptions.**
 - **we encourage healthcare professionals to fully explain patients' medicines at the point of prescribing and supply. This should include giving guidance and warnings of the potential for dependence and actions to take, appropriate to the patient's needs.**
2. The coronavirus (COVID-19) pandemic has highlighted the need to be able to access controlled drugs rapidly to manage people's end of life care. Mechanisms were quickly put in place by holding stock in 'hot hubs', but we must now learn from this for the future. To achieve this:
 - **CCGs should consider putting in place local arrangements to enable rapid mobilisation of medicines needed for end of life care in readiness for any future situation where the health and care system may come under similarly significant pressure.**
3. The failings at Gosport War Memorial Hospital were the result of a blanket approach to prescribing end of life medicines irrespective of the circumstances of individual patients. The lessons learned must not be forgotten as we now learn from our experiences during the peak of the COVID-19 pandemic. To achieve this:
 - **all healthcare professionals should consider the needs and wishes of patients and carers on an individual basis, particularly at the end of their life.**

Progress on 2018 recommendations

In last year's report on activity during 2018 we made four recommendations to improve the management of controlled drugs, and we now report on the progress against them.

Recommendation 1: NHS England should review the resourcing of its lead CDAOs and support functions as part of restructuring arrangements, to enable them to fulfil their statutory responsibilities effectively.

Progress: 2019 was a year of change for NHS England because of the restructuring with NHS Improvement – now referred to as NHS England & NHS Improvement (NHSE&I). From 1 April 2020, there are now 10 lead CDAOs.

Recommendation 2: NHS England CDAOs need to determine what information they all need from their local intelligence network members and request it in a consistent way.

Progress: NHS England lead CDAOs have worked collaboratively to standardise the information they need from their local intelligence network members, and there was wider adoption and use of the reporting tool during 2019.

Recommendation 3: CDAOs and nominated controlled drug leads must have oversight of the use of controlled drugs and follow up any unusual use, to assure themselves that the arrangements for controlled drugs in their organisation are safe. This should include timely audits and considering treating controlled drugs as high-risk medicines.

Progress: Many discussions at CDLIN meetings during 2019/20 addressed opioid prescribing and the use of audits to identify outliers and improve prescribing practice. CDLIN meetings included presentations by organisations that have developed local monitoring/auditing systems and influenced practice.

The Prescribing Sub-Group of the Controlled Drugs National Group has shared prescribing data and discussion outcomes with NHSE&I lead CDAOs, who have all taken steps regionally to address areas where high prescribing has been identified.

MHRA has also convened an Opioid Expert Working Group, which has made recommendations to add warnings to product labelling, packaging and patient information leaflets to increase awareness of the risks of dependence and addiction.

Recommendation 4: CDAOs and nominated controlled drug leads need to share controlled drug-related concerns about health and care professionals with their NHS England CDAO. Although it is important to be aware of GDPR requirements, these do not remove this responsibility in the interest of patient and public safety.

Progress: There is still a reluctance by some members to share information and concerns about misuse and diversion by healthcare professionals at CDLIN meetings. However, we are aware that personal information is now being shared more regularly outside of the CDLIN meeting and passed to appropriate organisations as some members regard this as a more confidential route.

Recommendation 5: All healthcare professionals need to remember their responsibility to speak up on areas of concern that might negatively affect patient safety, including prescribing, administering, dispensing, supplying, and disposing of controlled drugs.

Progress: Although we have no evidence to suggest that healthcare professionals are not speaking up about concerns, all CDLINs held discussions with network members during 2019 on the findings of the Gosport Inquiry. Many of the discussions included the importance of speaking up on areas of concern that may affect patient care and/or harm.

CQC's oversight activity in 2019

Register of controlled drug accountable officers

We maintain and publish an [online register](#) of controlled drugs accountable officers (CDAOs) across England for those organisations that are registered with CQC and are required under the 2013 Regulations as amended to have one. We update this register monthly. These organisations are defined as designated bodies under the regulations and are required to notify CQC of their CDAO appointment.

Throughout 2019, there was an average of 982 organisations on our CDAO register and we received approximately 27 notifications each month. Of these, 726 CDAOs were from independent healthcare organisations, 228 were from NHS organisations and the others from organisations such as social care providers that fall within the designated body status.

To keep the CDAO register up to date, it is important that organisations tell us about any changes to their CDAOs' details. If an organisation re-registers with CQC, it needs to submit a new CDAO notification. Notifications can be made using the [online webform](#). Changes to contact details such as email address or phone numbers can be emailed to CDAORegisterData@cqc.org.uk.

We grant exemptions for the need to have a CDAO, but uptake by eligible organisations continues to remain very low since becoming available in the Controlled Drugs (Supervision of Management and Use) Regulations 2013. Since 2013, we have granted:

- 38 exemptions for independent healthcare organisations with more than 10 employees, but where it was disproportionate to appoint one as there is a low use of controlled drugs
- 13 exemptions for organisations with fewer than 10 employees.

A very small number of organisations are registered solely with the Human Fertilisation and Embryology Authority (HFEA), and not with CQC. HFEA maintains a [register of CDAOs](#).

We also provide other information for CDAOs on our [website](#).

NHS England area teams and controlled drug local intelligence networks

During 2019, NHS England continued its integration with NHS Improvement and the move to seven regions. The new structure and CDAO provision became effective from 1 April 2020. As part of the integration, there is now a lead role that will bring all NHSE&I CDAOs together and provide greater consistency across all the regions. We do not yet know the full implications of the new structure or the resources available to the NHSE&I CDAO teams. However, sufficient resource needs to be maintained to enable them to deliver their responsibilities effectively.

Over the year, NHS England CDAOs have worked more collaboratively, meeting together regularly as an overall group as well as in smaller working groups to concentrate on specific tasks. The systems developed for sharing intelligence such as patient alerts, national and local related news and guidance, are working well and leading to more consistent messages at all controlled drug local intelligence network (CDLIN) meetings. Apart from one region, use of the national controlled drug reporting tool has resulted in greater consistency of the information requested and shared at CDLIN meetings. However, allocation of local resources across the country remains inconsistent, as some NHS England CDAOs have only minimal support.

Several CDLIN boundaries changed during 2019 because of the re-alignment and merging of smaller neighbouring networks. In 2019, there were 37 NHS England CDLINS across the 14 NHS England areas, which met between two and four times during the year. Most meetings included at least one area-wide CDAO training event. CQC attended around 76 CDLIN meetings and contributed a written meeting update when unable to send a representative.

CDLINS were attended by both designated and responsible bodies and they remain an effective way to share intelligence and learning as well as providing valuable networking opportunities. Where attendance at meetings has slipped, NHS England CDAOs are now proactively following up with those organisations and re-engaging them in the process.

As one of its actions following the government's response to the report on the Gosport War Memorial Hospital, NHSE&I asked CQC to carry out a survey to look at the effectiveness of its CDLINS. This was as part of our national oversight role of the 2013 Regulations. The survey ran from 1 April to 7 May 2019 and was open to all organisations that are members of CDLINS. We received 481 complete anonymised survey responses and shared the findings with NHSE&I during the summer.

The results of the survey were largely positive, with the majority of respondents indicating that the CDLINS continued to be an effective and safe environment in which to share information. The respondents were confident that the information shared would be acted on; felt that the CDLINS provided good networking and learning opportunities and were effective in circulating relevant information and alerts. Some respondents suggested extending the membership to social care and primary care organisations, and there were views about the physical meeting, including location, boundaries and network size. NHSE&I are considering these comments and suggestions.

Main findings from CDLINS

The key discussions and findings from CDLINS in 2019 were broadly similar to those shared previously (see [Appendix A](#)).

Controlled Drugs National Group

The CQC-led Controlled Drugs National Group met in March, June and November 2019. Membership of the Group remained the same as in the previous year, comprising government departments, key regulators and agencies with a controlled drug remit. Key discussion topics included medicinal cannabis, on-going investigations by the Medicines and Healthcare products Regulatory Agency into diversion from the legal supply chain,

the roll-out of the electronic prescription service (EPS) system and the report on the Gosport War Memorial Hospital. NHSE&I CDAOs share a summary of the meeting notes to CDLIN members to keep them updated on current developments and policy initiatives.

We have published a separate summary of activity from the past year showing how member organisations contributed to the overall safer management of controlled drugs.

Sub-groups

The operational sub-groups to the National Group also met regularly during 2019 to address controlled drug-related policy, patient safety, thefts and fraud, and prescribing issues. Membership comprised NHSE&I lead CDAOs, specialist pharmacists and medicine safety officers, other government bodies, the NHS Business Services Authority, and chief pharmacists. Other healthcare professionals with relevant expertise were also invited as required. The outputs from the groups were shared through our National Group newsletter, which we published in July and December 2019. In April 2020, we also published a special edition to alert subscribers to COVID-19 related controlled drug guidance. The circulation of the newsletter continues to grow and now has a readership of around 13,000. You can subscribe to this newsletter from our [website](#).

Cross-Border Group

The Cross-Border Group for safer management of controlled drugs in the devolved administrations met in March and September 2019, following the National Group meeting. It included members with a controlled drugs remit, for example, the Controlled Drugs Accountable Officers' Network Scotland, the Health and Social Care Board of Northern Ireland, NHS Wales and the Health Products Regulatory Authority of Ireland. We also included members from The Channel Islands. The group discussed controlled drug issues that are common across the devolved administrations and those that cross borders. We include a summary of our cross-border colleagues' activity in our stakeholder report.

In November 2019, we surveyed members of the National and Cross Border Groups to gather views on the current meeting structure. The outcome is that from 2020, the Cross Border Group will integrate into the National Group. Similarly, the three sub-group meetings (patient safety, prescribing and vigilance) will be amalgamated into one meeting to enable all members to contribute across these key areas. However, the policy group will remain separate and convene when it is needed.

Main findings from inspections

The issues we find on inspection are broadly similar each year (see [Appendix B](#) for details).

Key issues in 2019

Opioid medicines

In our 2018 report, we raised concerns about the increasing number of prescribed opioids, which continued during 2019. In September 2019, Public Health England published an evidence review, [*Dependence and Withdrawal associated with some prescribed medicines*](#). The list of medicines included opioid pain medicines, the gabapentinoids, benzodiazepines and z drugs (medicines that act in a similar way to benzodiazepines), and also antidepressants. The review found that rates of prescribing are affected by factors such as the age and sex of patients, as this is higher for women and older adults. It also found that the rate and duration of prescribing, and prescribing of more than one class of medicine, increases with levels of deprivation for patients. These findings resonate with the prescribing maps published in last year's update and those in the prescribing trends section of this year's update.

The review made recommendations for a number of organisations, including CQC. We were asked to use prescribing data to inform our inspections of primary care services, and we are now developing prescribing indicators for total opioid load and gabapentinoid prescribing. We were also asked to consider the availability of accessible information for patients that includes information about the potential harms of medicines. We are ensuring this is part of our regulatory process and make some recommendations to prescribers in this year's update.

Gosport War Memorial Hospital

There was much activity during 2019 to consider the lessons learned from the findings of the independent panel into the failings at Gosport War Memorial Hospital and to implement the recommendations set out in the government response to the report. Reflection sessions were held at CDLNs and many organisations carried out their own reviews or conducted gap analysis to assess their own organisation.

Actions for CQC related to controlled drugs as well as the wider closed culture issue, such as reviewing our assessment of how providers meet their responsibility under the duty of candour, a review of our external oversight including looking at how we respond to feedback, and strengthening our assessment of how NHS trusts' learn from deaths as part of our inspection process.

Internally, we set up a forum to look at the lessons learned and shared them in a series of webinars accessible to all CQC staff.

We continue to review and strengthen our assessment of governance arrangements for medicines (including for controlled drugs) and have included seeking assurance from NHS trusts as part of our inspection of the well-led key question. We continue to work on controlled drug issues with partner agencies through our strategic National Group and associated sub group, and through our attendance at CDLNs. We also carried out a survey on behalf of NHS England to support one of its actions to assess the effectiveness of CDLNs.

Primary medical services provided online

We saw a general expected increase in online prescribing during 2019, which has expanded in every sense over the last few months due to the COVID-19 pandemic. At the present time, the majority of consultations in both NHS and independent services have been carried out remotely, and it is unclear whether some will continue in this way. We will be able to learn from the pandemic and gather examples of good practice where consultations have been of a high quality regardless of being held remotely.

However, as set out in last year's update, there can also be greater risks associated with this modality. This is particularly the case where the patient is unknown to the prescriber and where the remote consultation is conducted by completing a form rather than a conversation between prescriber and patient. This is compounded by the fact that private prescriptions for Schedule 4 and 5 controlled drugs are not currently required to be submitted to the NHS Business Services Authority and therefore cannot be monitored. This results in a clear lack of oversight of the appropriateness of the medicine and the quantity for the patient concerned.

We know that controlled drugs in these lower schedules, for example co-codamol, co-dydramol, codeine and dihydrocodeine can, like those in the higher schedules, lead to dependence; but more worryingly, we are seeing an increasing number of coroners' reports where large quantities have been prescribed and have led to a patient's death. However, we are discussing this with other agencies to see if current arrangements can be strengthened.

Cannabis-based products for medicinal use

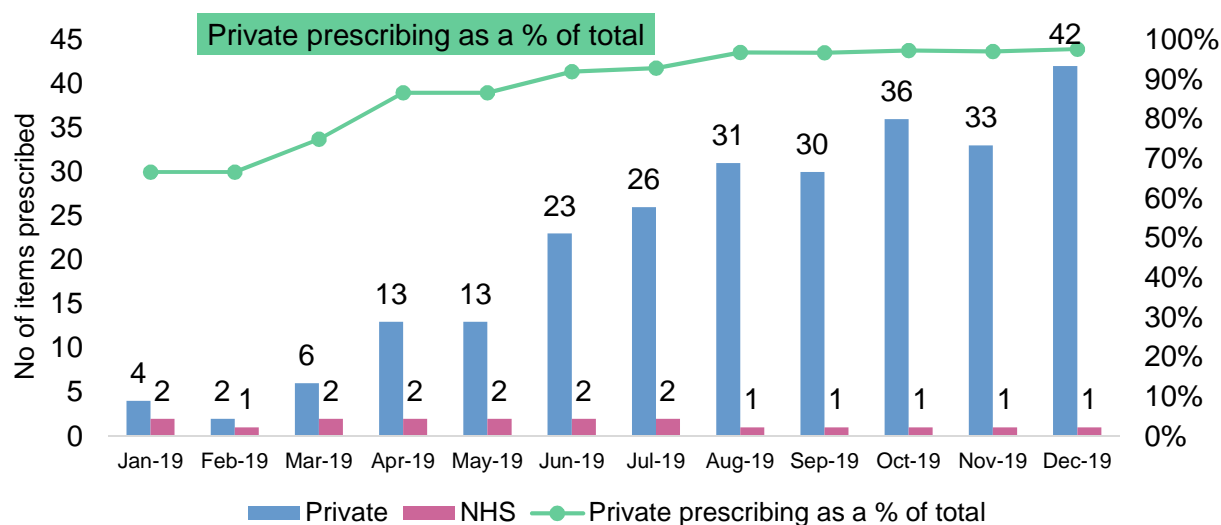
Cannabis-based products for medicinal use (CBPMs) continued to receive high-profile media coverage during 2019 and a number of independent clinics are now registered with CQC that provide treatment based on prescribing these products. There are now licensed CBPMs available in the UK, but some unlicensed products are also imported, mostly from Canada and The Netherlands, but also other countries including Australia.

CBPMs are Schedule 2 controlled drugs under the Misuse of Drugs Regulations 2001. Unlicensed CBPMs can only be lawfully prescribed by a doctor who is on the specialist register of the General Medical Council to treat patients with a specific unmet clinical need.

The number of prescriptions was low throughout 2019 but is increasing, with the majority of prescribing in the independent sector (figure 1).

Epidyolex, a cannabidiol-based product, was licensed in November 2019 as an adjunctive treatment for treating seizures attributable to Lennox Gastaut and Dravet syndrome. Before a marketing authorisation was granted, Epidyolex was available through the manufacturer's early access programmes, administered through specialist paediatric neurology tertiary centres. Prescribing during 2019 was minimal and episodic. Following assessment by the Advisory Council on the Misuse of Drugs, it was moved to Schedule 5 of the Misuse of Drugs Regulations 2001 on 24 June 2020, as the psychoactive constituent (tetrahydrocannabinol (THC)) is present only as an impurity, meaning it has a low risk of abuse potential, dependency and diversion.

Figure 1: Prescribing of cannabis-based medicinal products in 2019, in NHS and independent services



Coronavirus (COVID-19)

The COVID-19 pandemic has led to many consultations taking place remotely instead of face to face. The number of electronic prescription forms that GP practices sent through the electronic prescription service (EPS) in April 2020 increased by 34% compared with April 2019, with a corresponding decrease in the use of the paper prescription forms of 60%. This included controlled drugs in Schedules 2 and 3.

There has also been a need for services to have ready access to medicines for people at the end of their life. The usual route of supply against a prescription is often not quick enough, given the rapid deterioration of some patients. Clinical commissioning groups (CCGs) have therefore worked with partner agencies to ensure that there are systems and processes to ensure that the medicines required are available and accessible and can be directed quickly to a patient in the community without individual organisations needing to stockpile. The Department of Health and Social Care and NHS England and NHS Improvement published guidance to facilitate using patients' unused medicines in care homes and hospices under certain criteria.

Home Office legislation has also been introduced to allow a more flexible approach to supplying controlled drugs in certain situations during a pandemic (see below), but only after the Secretary of State has made an announcement and with the necessary NHS arrangements in place. These measures would only be used if pressures from increased demand and workforce illness/self-isolation during a pandemic meant that local health services were at imminent risk of failing to fulfil their duties.

However, it is essential that decisions around end of life care remain patient-centred and based on a person's individual needs, and that we do not adopt a blanket 'one size fits all' approach in our rush to manage patients' symptoms. In April 2020, CQC wrote to adult social care providers and GP practices with a [joint statement](#) prepared with the Care Provider Alliance, the Royal College of General Practitioners, and the British Medical Association about the importance of advance care planning being based on the needs of the individual. The statement emphasised that it is unacceptable to adopt a blanket approach to the use of Do Not Attempt Resuscitation (DNAR) or ReSPECT forms for groups of people.

We must not forget the very valuable lessons we have all learned from Gosport and be mindful that each person will have a different perspective on their care and treatment choices. These must be at the centre of all clinical decision making for that person and their family.

Legislation changes during 2019 and early 2020

The amendments to the Controlled Drugs (Supervision of Management and Use) Regulations 2013 removed the statutory expiry date and inserted a statutory review clause to ensure that the provisions of the regulations remain in force beyond 31 March 2020 (the details are in the [Statutory Instrument and Explanatory Memorandum](#)).

The Misuse of Drugs (Coronavirus) (Amendments Relating to the Supply of controlled Drugs During a Pandemic etc.) Regulations 2020 were introduced at the end of April 2020 to allow greater flexibility in the supply of controlled drugs. Although the amendments are enabling, they can only be used in limited circumstances and need to be authorised by the Secretary of State before they can be activated. In a pandemic situation, the amendments allow pharmacists at a registered pharmacy business to:

- supply medicines without a prescription, where the patient has been receiving a controlled drug in Schedule 2 to Part 1 Schedule 4 as part of ongoing treatment, and to supply Schedule 2 to Part 1 Schedule 4 controlled drugs under a Serious Shortage Protocol
- change the intervals on instalment prescriptions for Schedule 2 and 3 controlled drugs without the immediate need for a new prescription from an authorised prescriber under the 2001 Regulations, provided this is agreed with the prescriber or their appointed representative.

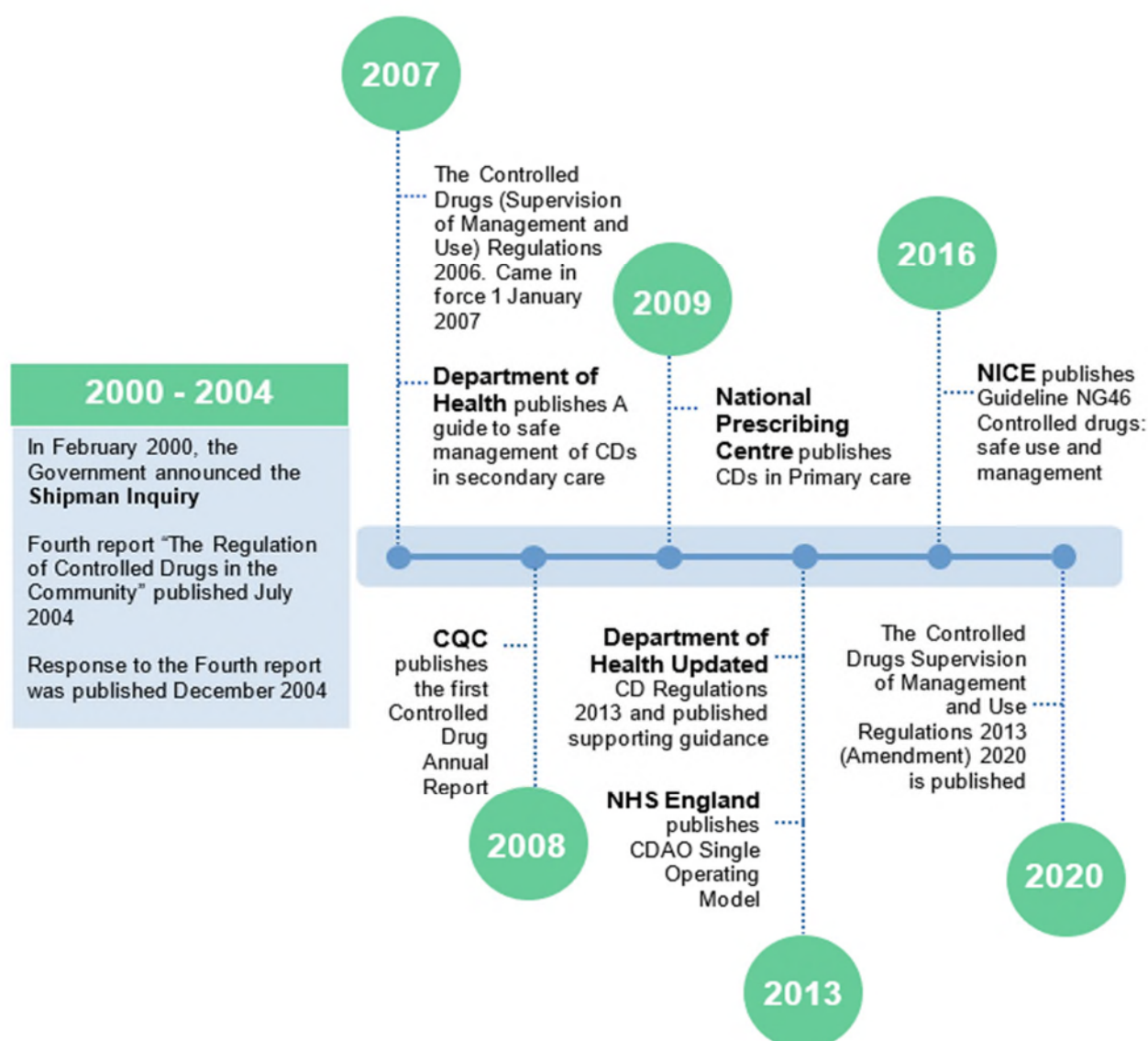
See the [Statutory Instrument and Explanatory Memorandum](#).

Development of controlled drugs legislation from 2000 to 2020

The current arrangements for the safer management of controlled drugs have evolved since the independent public inquiry to examine the issues arising from the case of Harold Shipman. The Fourth Report of the Shipman Inquiry focused on the methods Shipman used to divert large quantities of controlled drugs for his own purposes and considered how he was able to do it for so long without detection. It concluded that there were serious shortcomings in the systems for regulating the governance of controlled drugs.

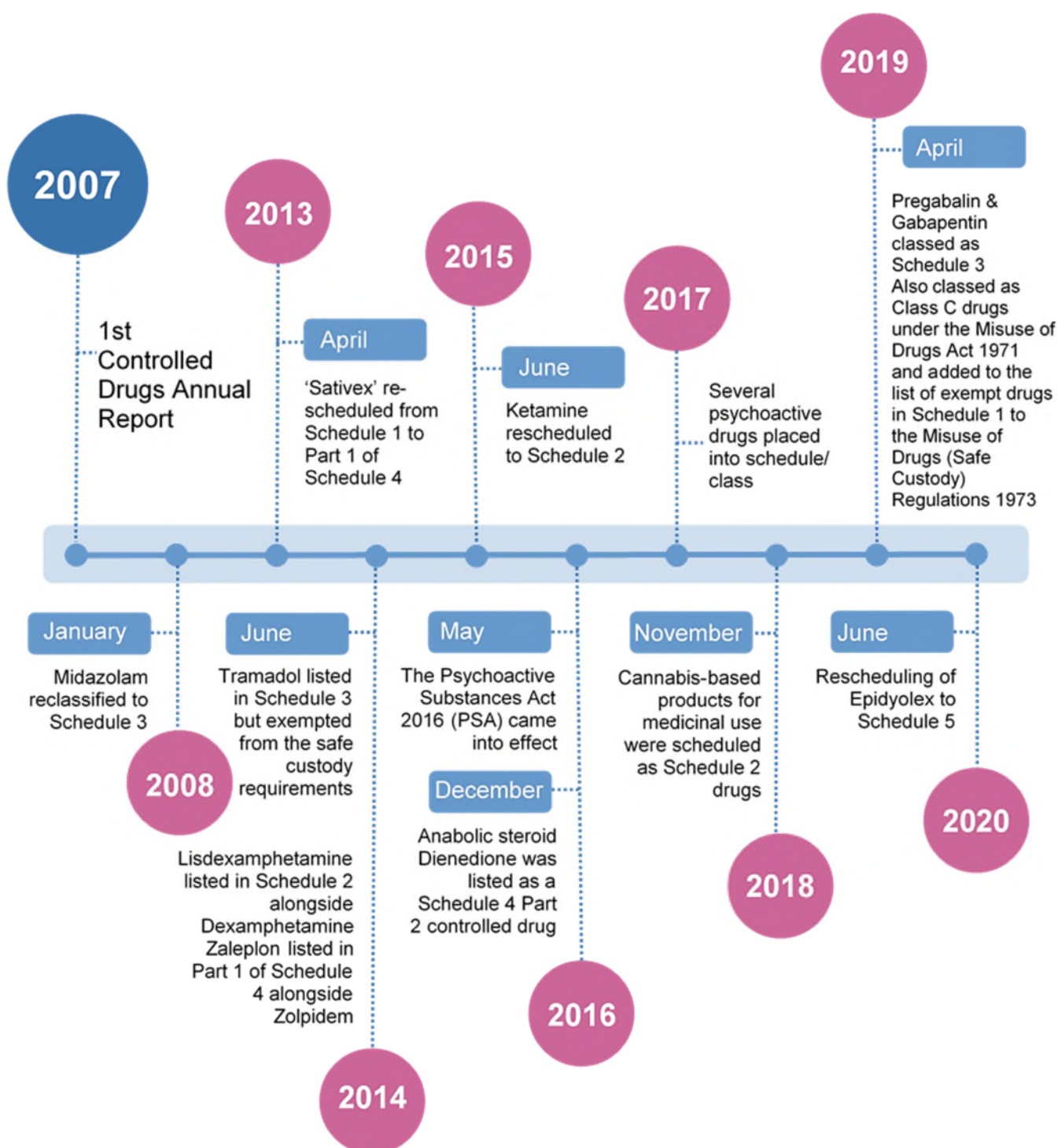
The Controlled Drugs (Supervision of Management and Use) Regulations 2006 were introduced in 2007, and accompanying guidance from the Department of Health set out the responsibilities of the former Healthcare Commission in relation to controlled drugs and external scrutiny of the new arrangements. The Care Quality Commission took on these responsibilities on 1 April 2009. Figure 2 shows the developments that have followed this.

Figure 2: Development of guidance and legislation on controlled drugs 2004 to 2020



We also take this opportunity to look at changes to the scheduling of controlled drugs introduced since the Controlled Drugs (Supervision of Management and Use) Regulations were introduced in 2007 (figure 3).

Figure 3: Changes to scheduling of drugs under the Misuse of Drugs Regulations 2001



National trends in the use and management of controlled drugs

Note on data: Data on prescribing in primary care is collected by an online application, which provides analyses of prescribing data held by NHS Business Services Authority to authorised users. The previous ePACT system (which gives access to prescription data to authorised users) was replaced by [ePACT2](#) in 2017. Data for year-on-year comparisons in this report have been extracted from ePACT2. Some data may differ from previously published data as ePACT2 continually updates, and data will differ from that extracted from the legacy system (ePACT).

Year-on-year, the prescribing trends for controlled drugs in NHS services are broadly similar, in general terms, for 2019 compared with 2018. However, the rescheduling of the gabapentinoids from 1 April 2019 has made a notable difference to the number of items prescribed in primary care, and accounts for 20% (14,694,891 items) of all items prescribed across Schedules 2 to 5.

During 2019, NHS primary care services prescribed a total of 71,717,719 controlled drug items, which was an increase of 17% compared with 2018. The cost of this was £542,719,577, an increase of 12% compared with the previous year. This increase in the number of items was larger than usual because of the rescheduling of the gabapentinoids to become Schedule 3 controlled drugs during 2019. However, if we exclude them, then the overall number of items would have decreased by 5%.

Hospital prescribing (on FP10HP prescription forms that can be dispensed in a community pharmacy) was also broadly in line with 2018, with 1,062,608 controlled drug items across Schedules 2 to 5 prescribed in hospital using an FP10(HNC) or FP10SS form. This is a 2% increase on 2018, with an increase in cost of 11%. Pregabalin and gabapentin were not classed as Schedule 3 drugs until April 2019, so are not included in the 2018 figures. Gabapentinoids accounted for just over 13% of all Schedule 3 items prescribed in 2019.

As 2019 was the last full year under the Controlled Drugs (Supervision and Management of Use) Regulations 2013, we have taken the opportunity to look at prescribing trends over the last five years. Between 2014 and 2019, the number of controlled drugs prescribed has risen by 23% from 58,212,105 to 71,717,719 (figure 4).

When split by schedule of controlled drug, we can see the volume prescribed in each schedule; by far the largest number of items prescribed were in Schedule 5 (figure 4).

Over the same period, actual costs fell slightly by 2% from £552,276,502 to £542,719,577 (figure 5). This reflects the upward trend in items prescribed and the downward trend in cost of prescribing.

Figure 4: Number of controlled drug items prescribed in NHS primary care by schedule (0,000s), 2014 to 2019

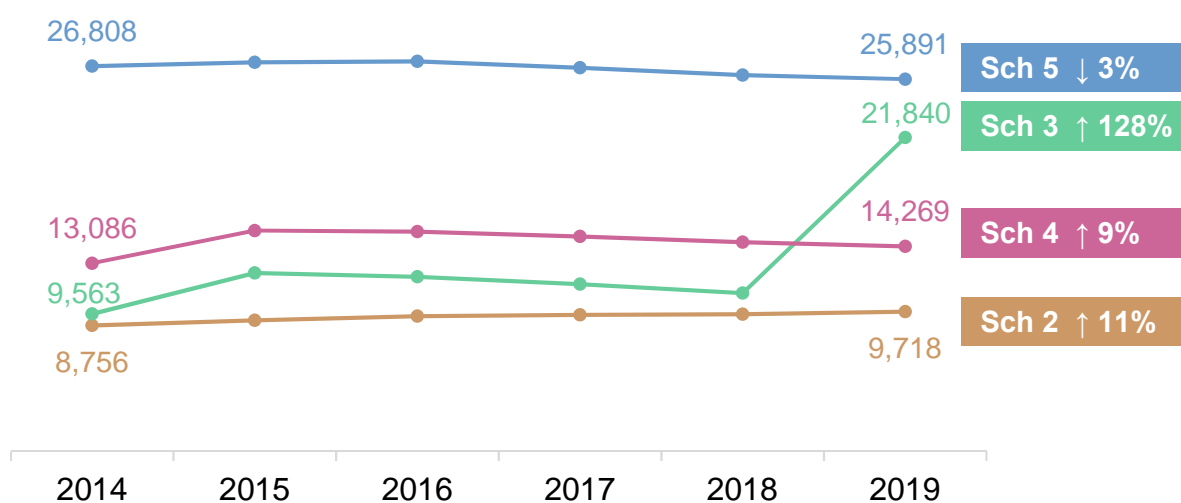
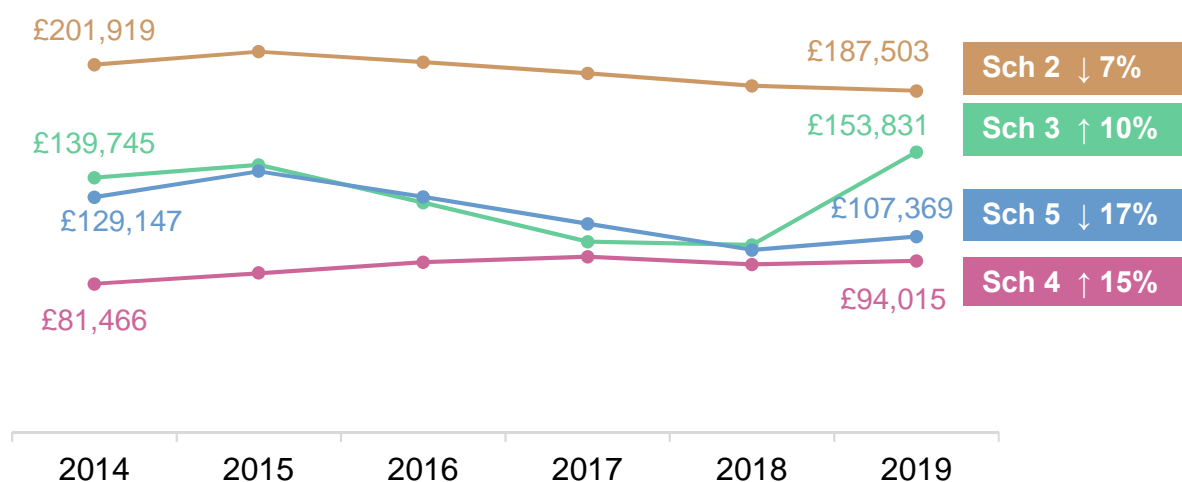


Figure 5: Cost (actual) of controlled drug items by schedule (0,000s) in NHS primary care, 2014 to 2019

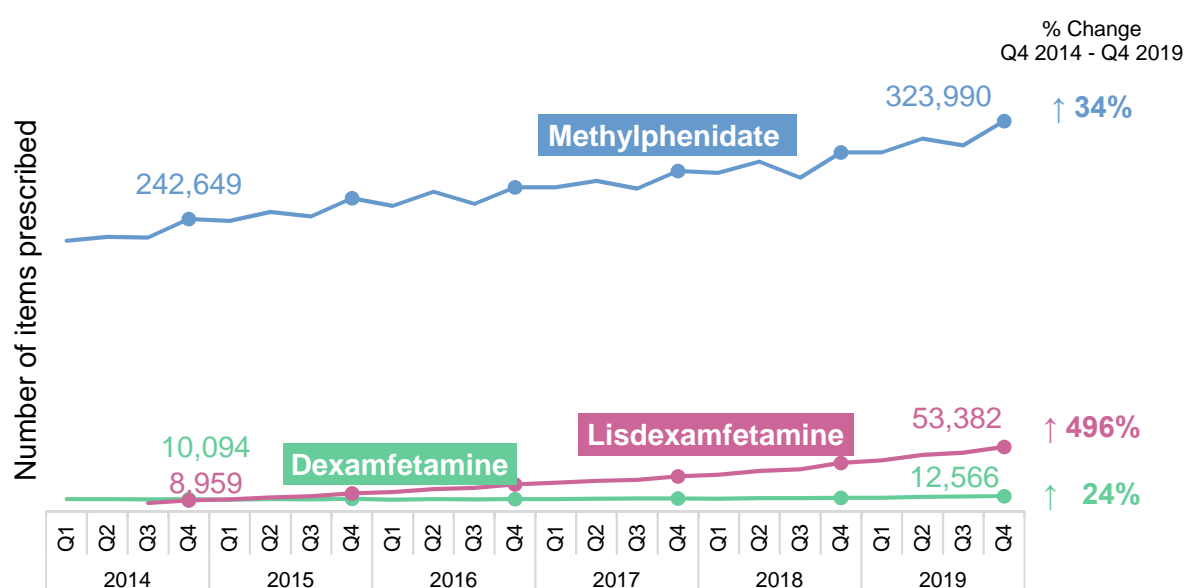


Schedule 2 controlled drugs

Over this period, although the number of Schedule 2 items prescribed increased (by 11%), it is the lowest number of items over the period compared with other scheduled drugs. However, the actual cost of Schedule 2 items is the highest compared with other scheduled items (£187,503,373 in 2019) although it fell by 7% between 2014 and 2019.

Looking specifically at medicines to manage ADHD, prescribing of dexamfetamine sulfate, lisdexamfetamine dimesylate, and methylphenidate hydrochloride increased between 2014 and 2019, with methylphenidate the most commonly prescribed (figure 6). Lisdexamfetamine became a Schedule 2 controlled drug in June 2014. Although we cannot provide a specific explanation for this year-on-year increase in prescribing, it is likely the result of various factors, including more awareness of, and therefore increased prescribing for the condition, and treatment of previously undiagnosed adults.

Figure 6: Prescribing of medicines used to treat ADHD in NHS primary care, 2014 to 2019



Notes: Q1 2014 has no data for lisdexamfetamine as it was not a controlled drug at that time, and Q2 data has been excluded as it is partial data (2,057 total items part Q2 2014).

The percentage change between 2014 and 2019 is calculated on Q4 of each year to take account of seasonal fluctuation in prescribing.

Schedule 3 controlled drugs

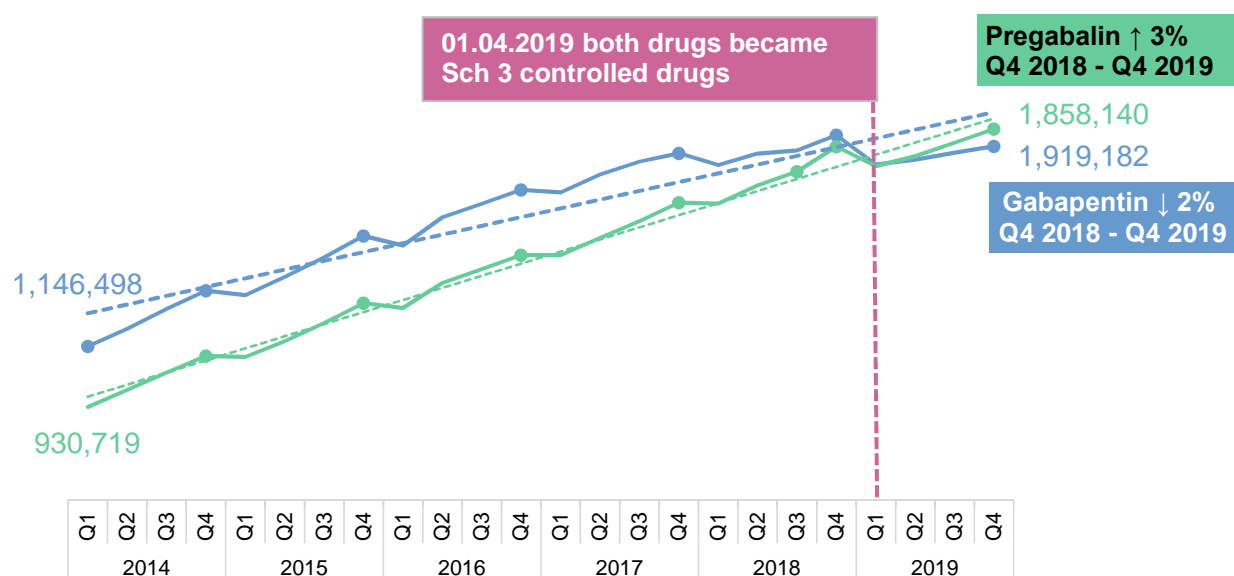
Overall, prescribing of Schedule 3 drugs increased by 128% between 2014 and 2019. The number of items prescribed in Schedule 3 showed a downward trend between 2015 and 2018 but, following the inclusion of gabapentin and pregabalin as Schedule 3 drugs from 1 April 2019, there was a 98% increase (10,822,340 additional items) over the previous year. The actual cost of prescribing Schedule 3 items in 2019 was £153,831,325, an increase of 50% (increased cost of £50,970,696), since 2018 and an increase of 10% in the five years from 2014.

Figure 7 on the next page shows the prescribing trend for the gabapentinoids over the last five years, although they only became a Schedule 3 controlled drug in April 2019.

There is seasonal fluctuation in prescribing with the highest prescribing in Q4 each year. Comparing like quarters, the increase in prescribing between Q4 2014 and Q4 2019 is 38% for gabapentin and 73% for pregabalin.

Comparing like quarters after being scheduled, prescribing of gabapentin decreased slightly by 2% between 2018 and 2019 and pregabalin increased by 3%. For the four-year period before being scheduled, prescribing of gabapentin increased by 41% and for pregabalin the increase was 67%.

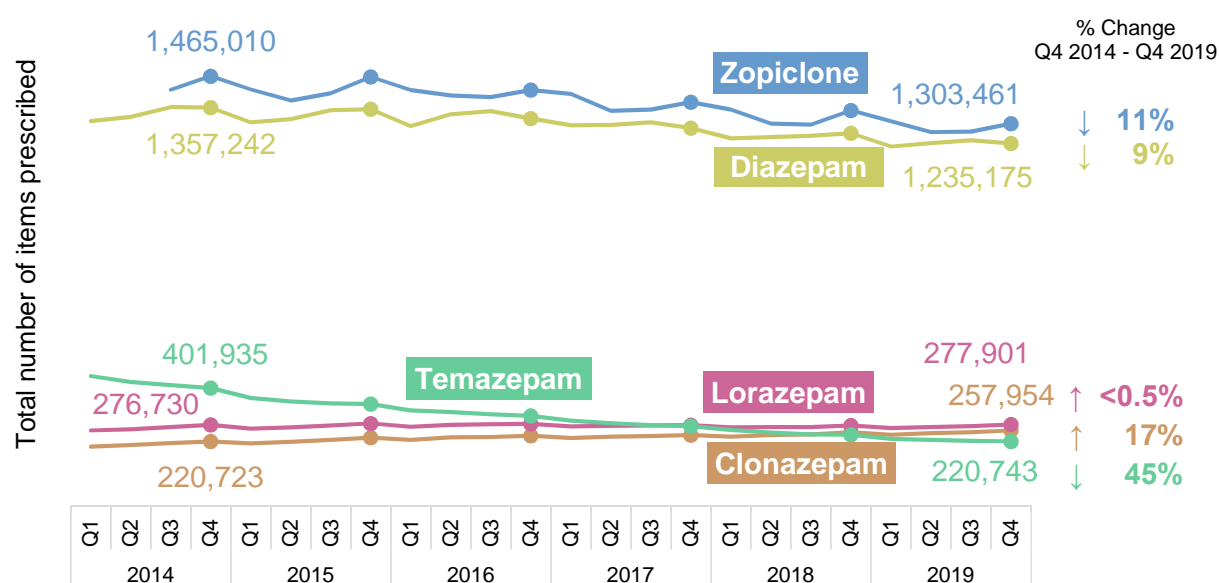
Figure 7: Prescribing of gabapentin and pregabalin in NHS primary care services, by number of items, 2014 to 2019



Schedule 4 controlled drugs

Prescribing of all Schedule 4 drugs increased by 9% between 2014 and 2019, from 13,086,306 to 14,268,597 items in total. Figure 8 compares quarterly prescribing patterns of benzodiazepines between 2014 and 2019. The top four (clonazepam, diazepam, lorazepam and zopiclone) prescribed in 2019 accounted for 86% of all Schedule 4 prescribing in quarter 4. Temazepam (a Schedule 3 benzodiazepine) has also been included for comparison and also reduced from 401,935 in quarter 4, 2014, to 220,743 items in quarter 4, 2019, a decrease of 45%.

Figure 8: Top four benzodiazepines and z drugs prescribed in Schedule 4 and temazepam prescribed in NHS primary care services, 2014 to 2019



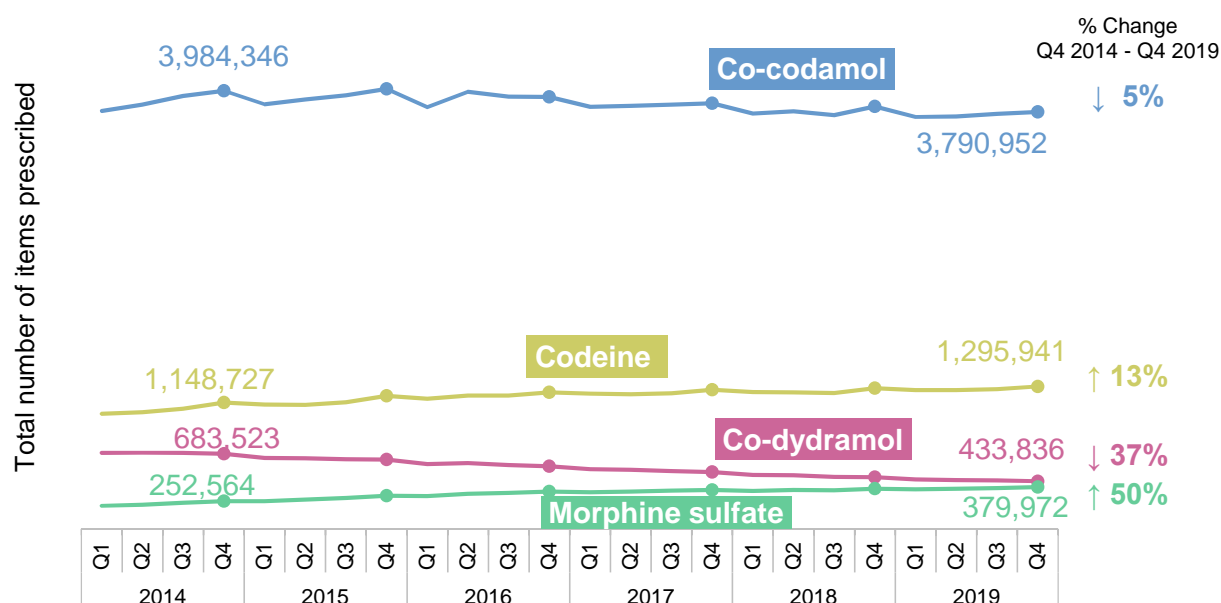
Note: Zopiclone became a controlled drug under Schedule 4 Part 1 in June 2014. Q1 2014 has no data as it was not a controlled drug at that time and Q2 data has been excluded as it is partial data (453,341 total items part Q2 2014).

The percentage change between 2014 and 2019 is calculated on Q4 of each year to take account of seasonal fluctuation in prescribing.

Schedule 5 controlled drugs

The prescribing of all Schedule 5 items decreased by 3% between 2014 and 2019, from 26,807,647 to 25,890,528 items. The top four prescribed Schedule 5 drugs in 2019 accounted for 90% of all Schedule 5 prescribing in the year. Figure 9 compares prescribing patterns of the top four items prescribed in Schedule 5 in 2019 over the period 2014 to 2019. The percentage change between 2014 and 2019 is calculated on Q4 of each year to take account of seasonal fluctuation in prescribing.

Figure 9: Prescribing of top four Schedule 5 items in NHS primary care, 2014 to 2019



Co-codamol (codeine phosphate/paracetamol) accounts for 58% of all prescribing of Schedule 5 controlled drugs. Prescribing of morphine sulfate 10mg/5ml oral solution has increased by 50% over the period, and codeine phosphate by 13%. These two accounted for 26% of all Schedule 5 prescribing in Q4 2019. For a full breakdown of the top 10 items prescribed by schedule, see the [appendix](#).

Regional breakdown of prescribing

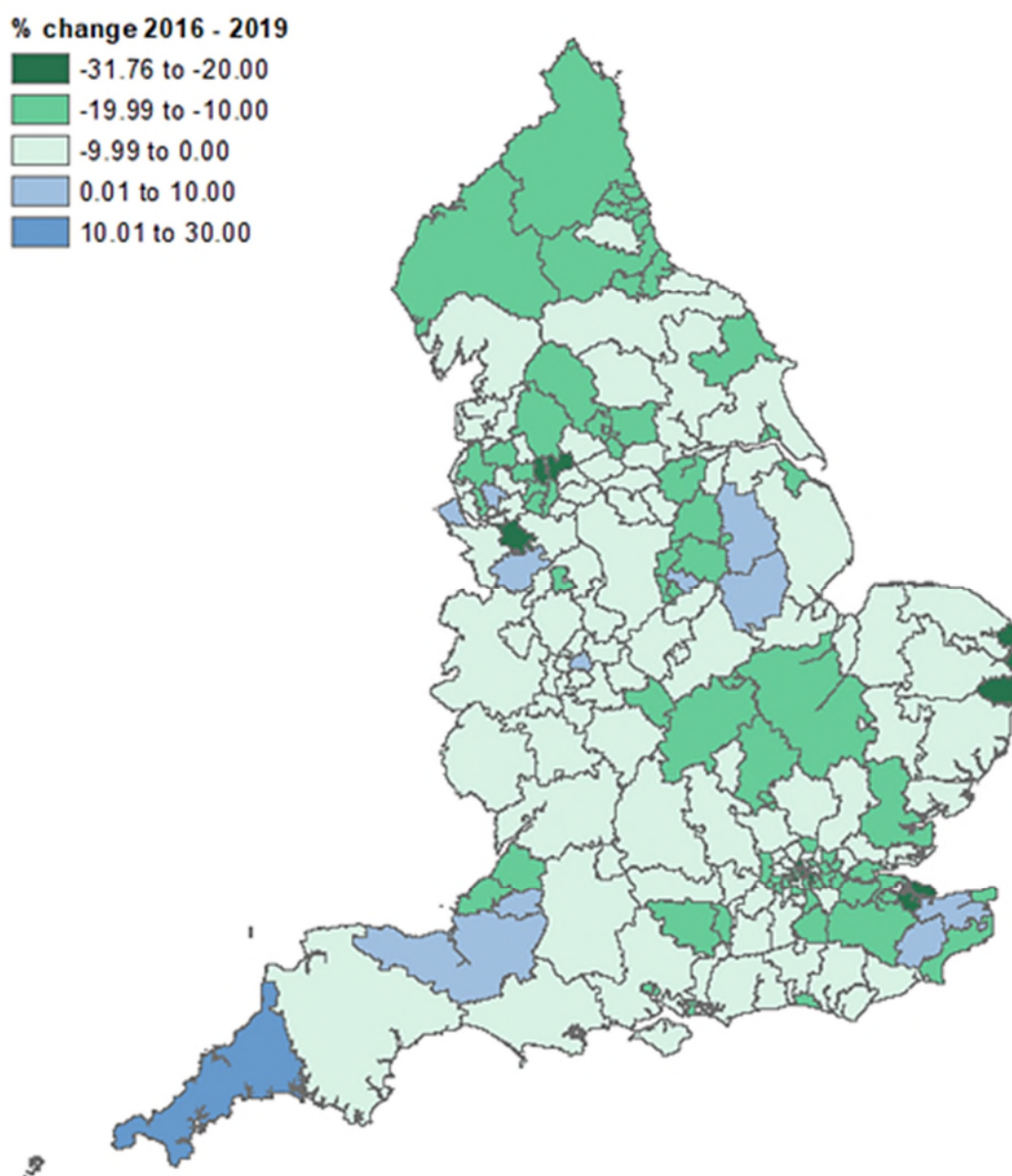
For the following three regional breakdown maps, we compare prescribing by clinical commissioning group (CCG) area, based on 191 CCGs operating in 2019. Changes to CCG areas since 2016 have resulted in eight fewer CCGs. Increases in prescribing are shown in shades of blue and decreases in shades of green.

Prescribing of a benzodiazepine and an opioid concurrently

Following on from the analysis we shared in last year's annual update, the prescribing patterns in CCG areas for a benzodiazepine and an opioid concurrently in 2019 was similar to those reported in 2018 (figure 16 in the appendix). Higher prescribing is evident in the north east, east and south west of England. There is lower prescribing in and around London, and through parts of the Midlands and south east.

The map in figure 10 shows the percentage change in prescribing by CCG area for the prescribing of a benzodiazepine and an opioid concurrently, using numbers of unique patients per 1,000 patients for the period 2016 to 2019.

Figure 10: **Prescribing of a benzodiazepine and an opioid concurrently per 1,000 patients; percentage change, 2016 to 2019**



Concurrent prescribing between 2016 and 2019 had decreased in 94% of CCGs (179), with 40% (76) of CCGs reducing co-prescribing of both substances by 10% or more.

The CCGs where concurrent prescribing has reduced the most since 2016 are:

- Hammersmith & Fulham CCG (-32%)
- Southwark CCG (-28%)
- Heywood, Middleton and Rochdale CCG (-26%)
- Central London (Westminster) CCG (-25%)
- Camden CCG (-24%).

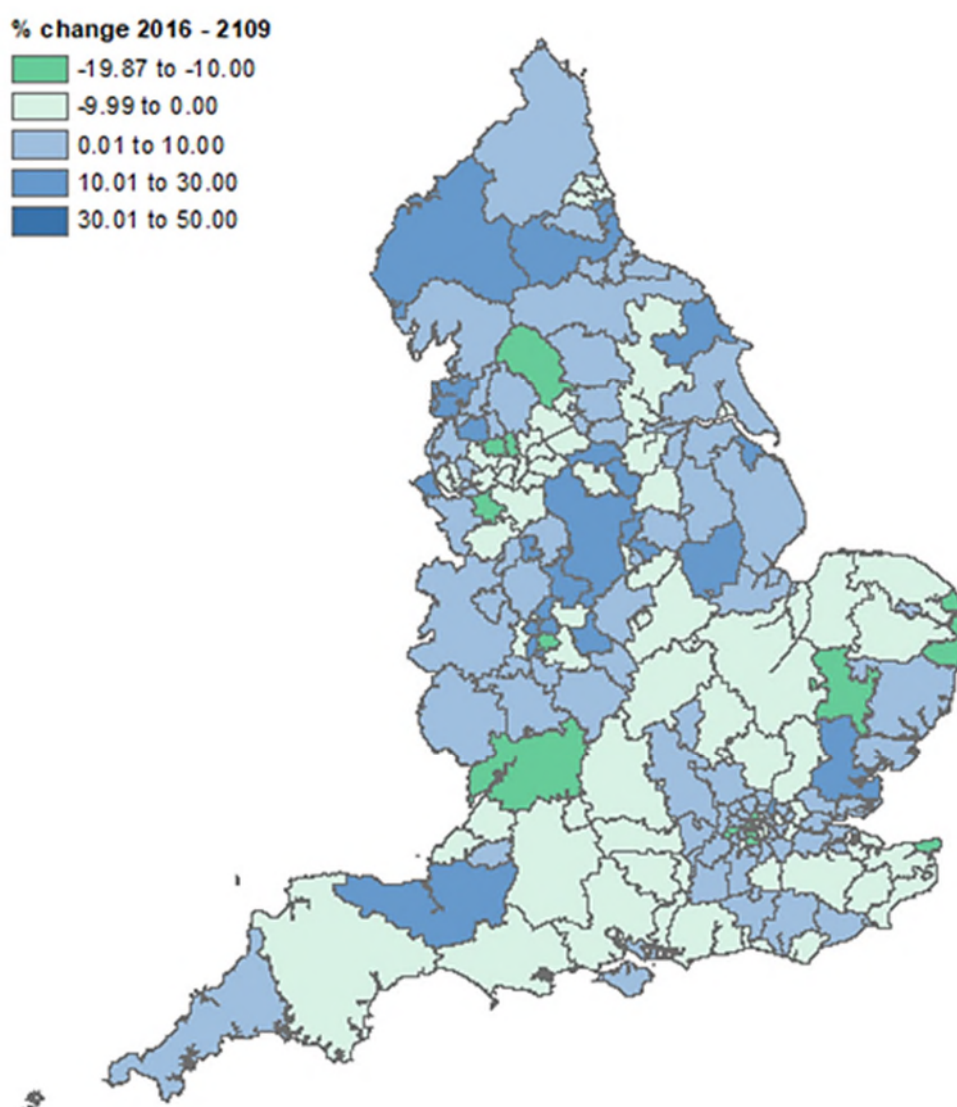
In 6.3% (12) of CCGs, concurrent prescribing increased since 2016 and Kernow CCG stands out as the area with the highest percentage increase in concurrent prescribing.

Prescribing of gabapentinoids and an opioid concurrently

Similarly, if we look at prescribing of the gabapentinoids with an opioid concurrently, 2019 prescribing was similar to that reported in 2018 (figure 17 in the appendix).

The map in figure 11 shows the percentage change in prescribing by CCG area for the prescribing of gabapentin and an opioid concurrently, using numbers of unique patients per 1,000 patients for the period 2016 to 2019.

Figure 11: Prescribing of gabapentin and an opioid concurrently per 1,000 patients, percentage change, 2016 to 2019



The greatest percentage change in concurrent prescribing is predominantly in the north of the country, the south west and a band around London in the South East and East.

The CCGs where prescribing has increased the most since 2016 are:

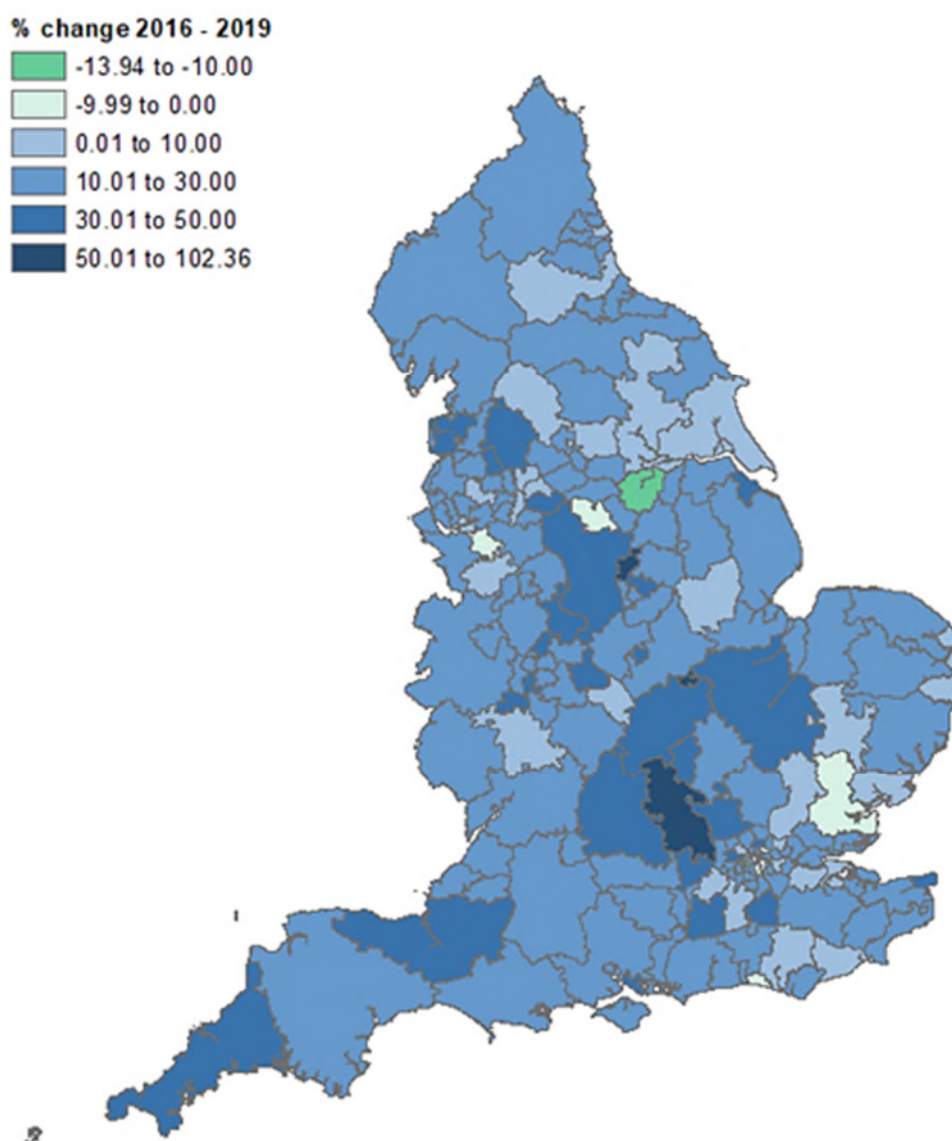
- Blackpool CCG (27%)
- Cannock Chase CCG (23%)
- Barnsley CCG (19%)
- North East Lincolnshire CCG (17%)
- Wolverhampton CCG (16%).

Of the CCGs, 56% (107) have increased concurrent prescribing since 2016, with 13% (25) of all CCGs increasing concurrent prescribing by 10% or more.

Prescribing of pregabalin and an opioid concurrently

For prescribing of pregabalin with an opioid concurrently, prescribing in 2019 was also similar to 2018 (figure 18 in the appendix). The map in figure 12 shows the percentage change in prescribing by CCG area for the prescribing of Pregabalin and an opioid concurrently, using numbers of unique patients per 1,000 patients for the period 2016 to 2019.

Figure 12: Prescribing of Pregabalin and an opioid concurrently per 1,000 patients, percentage change 2016 to 2019



The CCGs where concurrent prescribing has increased the most since 2016 are:

- Buckinghamshire CCG (103%)
- Corby CCG (80%)
- Mansfield and Ashfield CCG (51%)
- North East Lincolnshire CCG (47%)
- Wyre Forest CCG (46%).

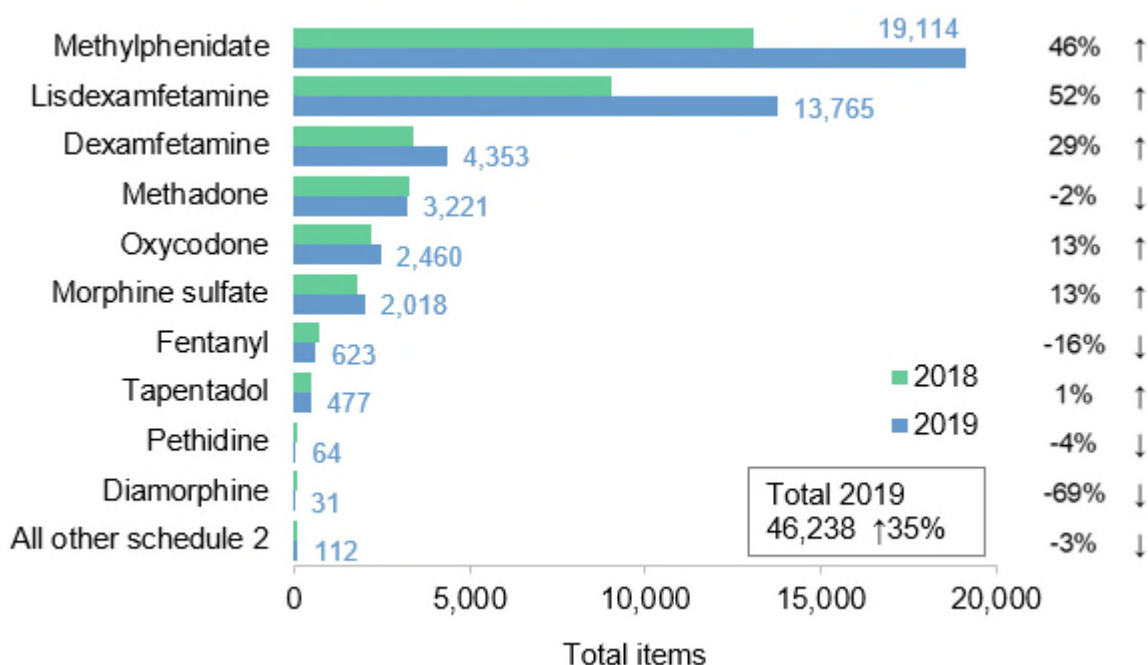
Concurrent prescribing increased in 95% (181) of CCGs since 2016, and 44% (84) of CCGs increased concurrent prescribing by 20% or more.

Generally, there is a pattern that the areas that have increased concurrent pregabalin and opioid prescribing are those that have decreased concurrent gabapentin and opioid prescribing, with some exceptions.

Prescribing in independent primary care providers

The prescribing picture in independent or private primary care is broadly similar to that of 2018. Overall it represents 0.1% of all FP10, hospital, private and requisitions prescribing, which is the same figure as last year (figure 13).

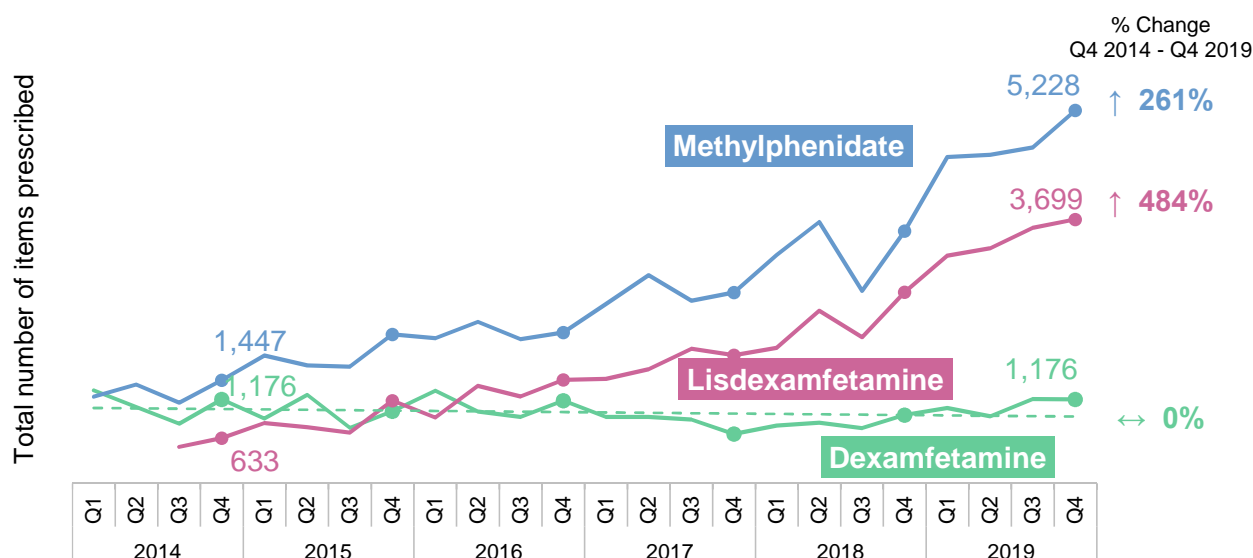
Figure 13: **Top 10 Schedule 2 controlled drugs privately prescribed in 2018 and 2019**



Lisdexamfetamine became a controlled drug under Schedule 2 in June 2014.

As both methylphenidate and lisdexamfetamine are the top two Schedule 2 controlled drugs prescribed privately, we highlight the trend over time (figure 14).

Figure 14: Private prescribing of medicines used to treat ADHD, 2014 to 2019

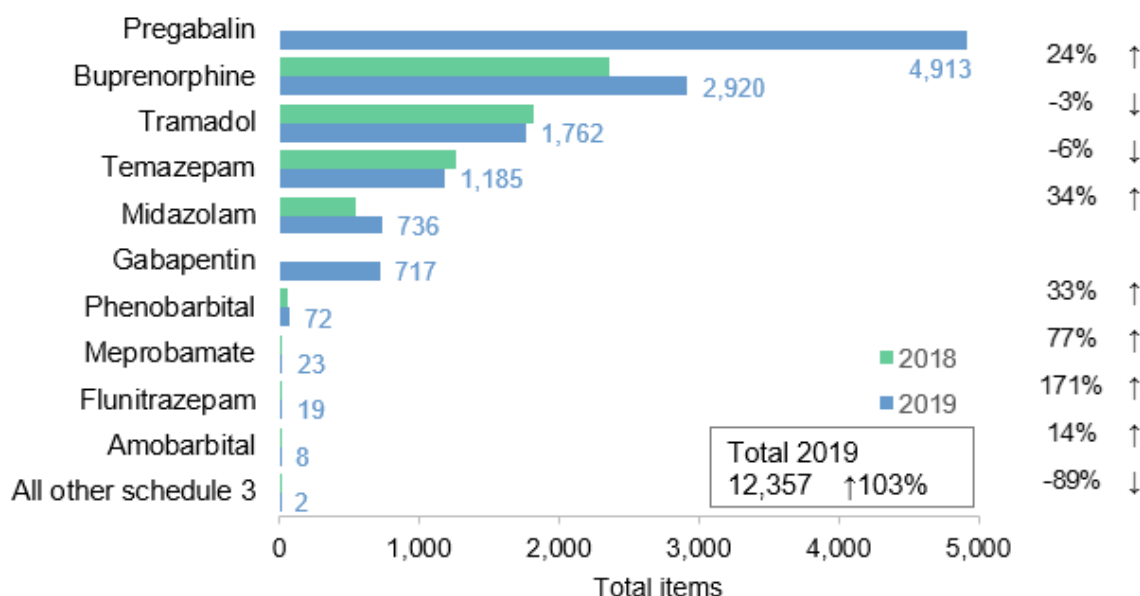


Note: Q1 2014 has no data for Lisdexamfetamine as it was not a controlled drug at that time and Q2 data has been excluded as it is partial data (188 total items part Q2 2014). The % change between 2014 and 2019 is calculated on quarter 4 of each year to take account of seasonal fluctuation in prescribing.

As in NHS primary care, methylphenidate is the highest prescribed, while dexamfetamine prescribing remains comparatively low and has remained more or less static over this period.

For Schedule 3 controlled drugs prescribed privately, pregabalin is the most prescribed and gabapentin is also in the top six (figure 15).

Figure 15: Top 10 Schedule 3 controlled drugs privately prescribed in 2018 and 2019 (number of items)



Non-medical prescribing

As in previous years, prescribing by non-medical prescribers increased in 2019, with the most significant increase from pharmacist prescribing, which increased by 80% over the previous year. Nurse prescribing also increased by 32%.

Although there was also more prescribing by physiotherapists, with prescribing increasing by 96%, overall the numbers still remain very small (687 items). Prescribing by podiatrists decreased by 45% to 83 items. For the first time, prescribing by paramedics is included in the non-medical prescribing data. In 2019, paramedics prescribed 689 items. However, paramedic prescribing of controlled drugs is currently only permitted through supplementary prescribing under a clinical management plan.

Conclusion

During 2019, we continued to look at the themes identified in 2018 around opioid prescribing, the increasing use of remote prescribing by online services, the lessons learned from Gosport, and the emergence of independent clinics offering cannabis-based medicinal products.

We then faced the challenge of the COVID-19 pandemic, starting in the first quarter of 2020, something for which we had little warning and for which we needed to adjust arrangements at short notice. There has been a great deal of learning and quality improvement by default as the Nightingale Hospitals began to be equipped and opened in some of our bigger cities, and policies and guidance were introduced to enable medicines to get to patients irrespective of the setting.

Health and care providers acted quickly in response to the pandemic, however, as the pressure on healthcare systems increased, there were at times risks to the controlled drug governance arrangements that have been established since the time of the Shipman Inquiry. Risk assessments and some very pragmatic approaches and work-arounds were implemented quickly, as services had to adjust to the demands placed on them. However, it is essential that decisions around end of life care remain patient-centred and based on a person's individual needs, and that we do not adopt a blanket 'one size fits all' approach in our rush to manage patients' symptoms. We must not forget the learning from Gosport and the need to place the wishes of patients and their families at the heart of clinical decision making, particularly when managing care at the end of life.

There now needs to be a period of reflection on what went well, what went less well and what we would do next time. We also need to future-proof some of the learning so that we are as well-prepared as possible for any future situation where the health and care system may come under similarly significant pressure.

Appendix A: Key concerns discussed at CDLIN meetings

1. Lack of centralised systems

- There is a risk of inappropriate and duplicated prescribing of controlled drugs to temporary residents. There is no central register of temporary residents for prescribers to check.

Solution to consider: A central patient database accessible to prescribers would be welcome, so that patients who try to access controlled drugs from more than one service could be easily identified and supported where required.

- Because of changes in primary care support services there are risks associated with lack of oversight and control of secure stationery to private prescribers.

Solution to consider: The governance arrangements for issuing prescription pads need to be strengthened to avoid over-ordering and potential misuse.

2. Information governance

- There is a general lack of clarity on issuing controlled drug alerts, particularly regarding the level of detail that should be included.

Solution to consider: NHS England CDAOs are working together to share alerts and work is still on-going to include all relevant parties including cross border organisations.

3. Theft and diversion

- Theft and diversion of controlled drugs by some healthcare professionals continues to be a regular theme at CDLIN meetings. Methods of diversion have included:
 - former staff using their old ID passes and badges to obtain supplies from community pharmacies
 - misuse of private controlled drug PIN codes and prescription stationery to obtain controlled drugs for personal use or for family members
 - diversion of controlled drugs from hospital wards and departments for personal use or for onward supply
 - larger scale diversion of controlled drugs from the legal supply chain by theft from delivery vehicles.

Solutions to consider: Encourage staff to be vigilant and know how to report concerns, strengthen security arrangements around controlled drug stationery, ensure all human resources checks are carried out both pre-employment and once an employee has left or retired (including return of ID badges, keys and passes and uniform) and Implement effective systems for checks and monitoring controlled drugs.

4. Wrong medicine/wrong patient

- There have been reports at several CDLIN meetings where a patient has either received someone else's methadone or a patient has had their medicines delivered to the wrong address.

Solutions to consider: Ensure patient identity checks are carried out when giving out all medicines, provide training and competency assessments for staff delivering medicines to patients' homes (including volunteers), establish a system of checks to verify a person's identity before handing over medicines, including all controlled drugs – even if the patient looks familiar.

Appendix B: Controlled drug issues found on inspection

1. Governance issues

- CDAO notifications: The details of the CDAO on the register do not match those of the CDAO in post – particularly when the CDAO has recently moved to a new role.

We expect a [timely notification](#) so that the register is up to date to enable the CDAO to be contacted as required.

- Home Office licences for controlled drugs: There is often a lack of understanding of when a Home Office licence is required and for what schedules, and a lack of awareness that there are licences for both Home Office possession and Home Office supply, which providers may need to apply for.

Organisations must seek their own advice. We expect to see evidence on inspection to show that the Home Office has been contacted where a [licence](#) might be required.

- Lack of awareness of relevant guidance and safety alerts: Many queries to CQC can easily be answered by referencing the [NICE guidance NG46](#), safety alerts and other sources of information and evidence-based resources such as PresQIPP.

Organisations should be familiar with relevant guidance and ensure that they cascade it where required. We would like to see on inspection how this has been implemented in wards or departments.

- Reporting incidents and concerns: There is a general lack of awareness of who to report incidents to (either to the organisation's CDAO, the MSO, the NHS England lead CDAO for the area, CQC, other professional and regulatory bodies, the police or the NRLS).

We expect organisations to have a standard operating procedure in place that explains all ways to report and that encourages open reporting and a non-blame culture. We also expect to see evidence of incidents and the learning from them.

- Illicit substances: This issue is becoming more apparent and we are aware of more frequent and increasing quantities being brought onto healthcare premises. We are also aware of some emerging trends, such as patients bringing in their own supply of cannabis containing products such as CBD oil.

Organisations need to have a clear procedure and maintain a robust audit trail with secure, sealed containment of unknown substances. A small amount can be destroyed locally as an unknown substance. Larger quantities (not for personal use) will need to be notified to the police. Particular trends should be communicated to the NHS England CDAO so they can share the issue and any learning with the CDLIN.

2. Ordering issues

- Controlled drug mandatory requisition form: There is a general lack of understanding of when to use the form. Services are also sometimes unaware that a doctor must sign the requisition if supply is from a separate legal entity.

Providers need to follow guidance on the NHS BSA website. We expect the organisation to be aware of the requirements set out in MDR 2001.

3. Record keeping issues

- Records: These are generally completed well, although there is sometimes confusion between the controlled drug register and controlled drug record books in wards and departments.

There should only be one controlled drug register at the premises.

- Controlled drug record books: Not all theatres follow the good practice requirement to complete the amount used/amount wasted.

We expect organisations to adopt good practice initiatives.

4. Storage issues

- We find that some organisations still store controlled drugs in wooden cupboards, which do not meet the minimum standard.

We expect organisations named in [The Safe Custody Regulations 1973](#) to comply with the regulations, and organisations outside the scope to use the requirements as a minimum standard.

- Sometimes the contents of the cupboard do not match what is in the register. This is not usually a stock issue but related to a patient's own or 'just in case' medicines for end of life care.

All drugs stored in a controlled drugs cupboard must be recorded appropriately.

- Not all organisations separate high and low strength preparations or those intended for different routes such as epidurals and intravenous injections, which can increase the risk of selecting and administering the wrong preparation.

We expect organisations to carry out their own risk assessment and incorporate relevant guidance into their processes.

- Some organisations are unsure how to manage situations where neither the legislation nor guidance covers the exact situation they are dealing with, for example, where controlled drugs are stored in a fridge or robot, or where there is no solid wall to affix the cupboard.

We expect a documented risk assessment to be in place. Above all, controlled drugs must remain secure, for example, a separate secure container for controlled drugs that need refrigeration, or secure storage within a robot. An exemption certificate issued by the police may also be required.

Where there is no solid wall, other measures should be considered, for example, strengthening an internal wall or reviewing the location of the cupboard, and the decision recorded in a risk assessment that is reviewed regularly.

- Access to keys and cupboards is generally managed well.

We expect a standard operating procedure to be in place that covers access to keys, and staff to adhere to it. We also expect to see monitoring in place as we are aware that controlled drugs are often diverted by those with legitimate access.

5. Prescribing issues

- Nationally, there is a general naivety regarding diversion issues.

It is important to minimise the quantity of a controlled drug prescribed and to regularly review the patient's ongoing need. It is particularly important to consider the quantity issued in an emergency and for temporary residents until checks are carried out.

- Organisations do not always consider the need for a reversal agent (a medicine that reverses the effect of the medicine administered to the patient).

We expect this to be considered as part of the prescription where appropriate, and it may need to form part of a clinical protocol.

6. Administration issues

- There is some uncertainty regarding administration of controlled drugs by a single nurse and the need for two signatures, and some organisations are unclear whether single nurse administration is allowed.

A single nurse can administer a controlled drug unless the local policy says otherwise. If a second checker is not a registered nurse, they must understand or be familiar with what they are being asked to check. We would expect to see that a competency assessment had been completed.

- Dose calculations are a common cause of errors – particularly with new formulations or devices.

It is important to have training and competency assessments for difficult calculations or unfamiliar devices. Clinicians should be encouraged to ask for a second check if they are unsure or unfamiliar with the product or formulation.

- Body maps are not always in place when applying transdermal patches. There is also a lack of awareness of the effect of heat, the importance of removing a previous patch and the need to check the patch every day.

Application and removal of transdermal patches continues to cause concern, and we expect to see appropriate arrangements in place to ensure that patches are managed safely.

7. Auditing and monitoring issues

- Some organisations are unaware of the importance of recording and auditing all stages of the controlled drug journey, and the need for standard operating procedures and ongoing regular review.

We expect the standard operating procedures to cover all aspects of controlled drug management and for these to be kept under review with supporting audits.

- We find insufficient monitoring and audit and are aware of thefts and diversion of controlled drugs, particularly those in lower schedules where there is less control, for example dihydrocodeine or morphine sulphate solution 10mg/5ml.

We expect organisations to risk-assess their controlled drug arrangements, with regular monitoring according to their organisational needs, to keep losses to a minimum.

8. Destruction issues

- Some organisations are unaware of the requirement to hold a T28 exemption form for denaturing controlled drugs.

Organisations that denature controlled drugs must obtain a [T28 exemption form](#) from the Environment Agency.

- There is uncertainty around disposing large volume infusions (for example, hospital PCAs etc).

Large-volume controlled drugs should be discarded using an absorbent material to soak up the liquid.

- Organisations are not always clear what to do with completed denaturing kits. These must be stored securely until removed for incineration.

Appendix C: Supplementary regional maps

Regional concurrent prescribing with an opioid in 2019

Figure 16: **Prescribing of benzodiazepine and an opioid concurrently in 2019, numbers of unique patients per 1,000 patients by CCG**

Prescribing patterns for CCGs in 2019 remain similar to those reported in 2018. Higher prescribing is evident in the north, east and south west. There is lower prescribing in and around London, and through parts of the Midlands and south east.

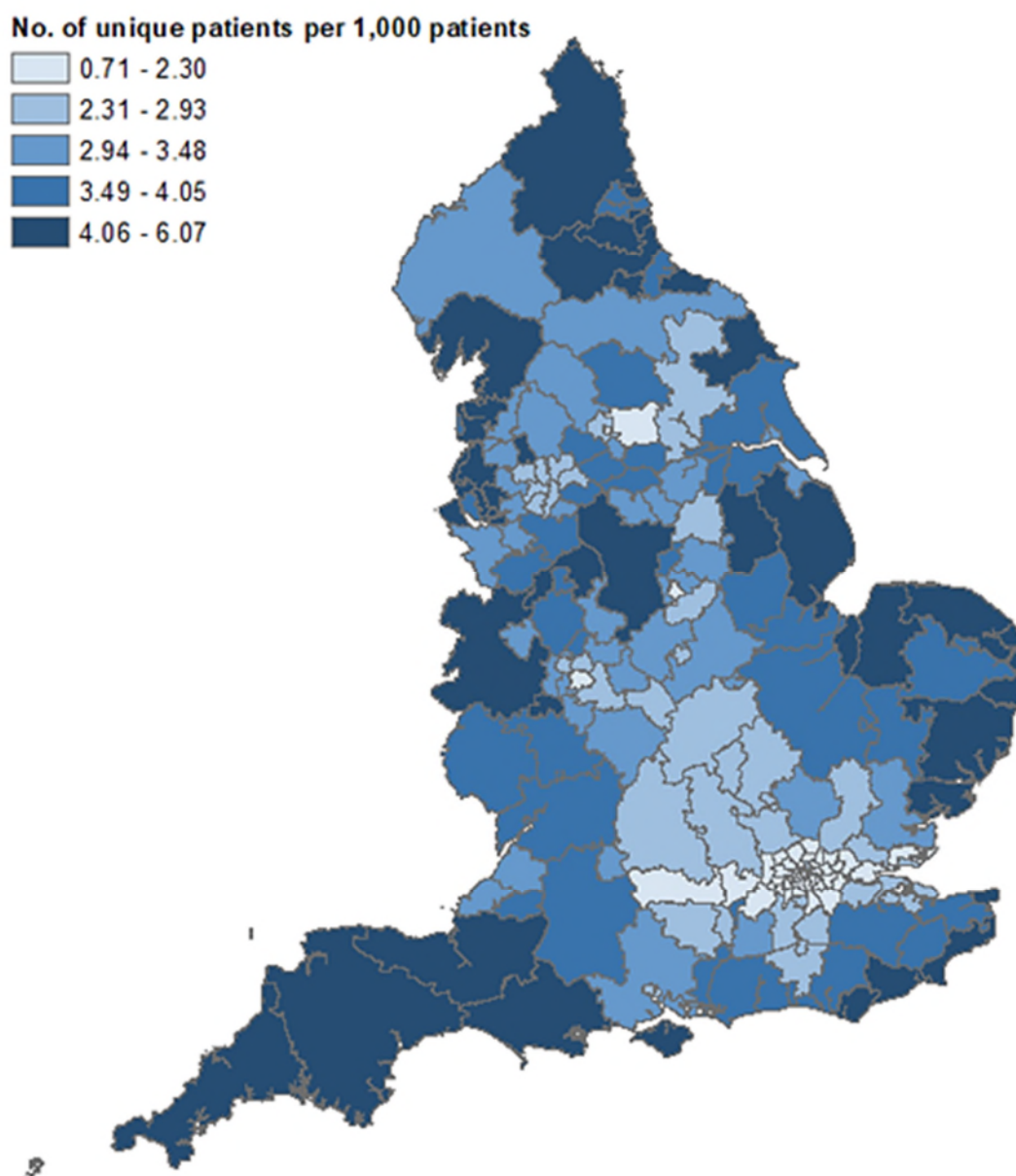


Figure 17: Prescribing of gabapentin and an opioid concurrently in 2019, numbers of unique patients per 1,000 patients by CCG

Prescribing by CCGs in 2019 is similar to those reported in 2018, with higher concurrent prescribing in the north of the country.

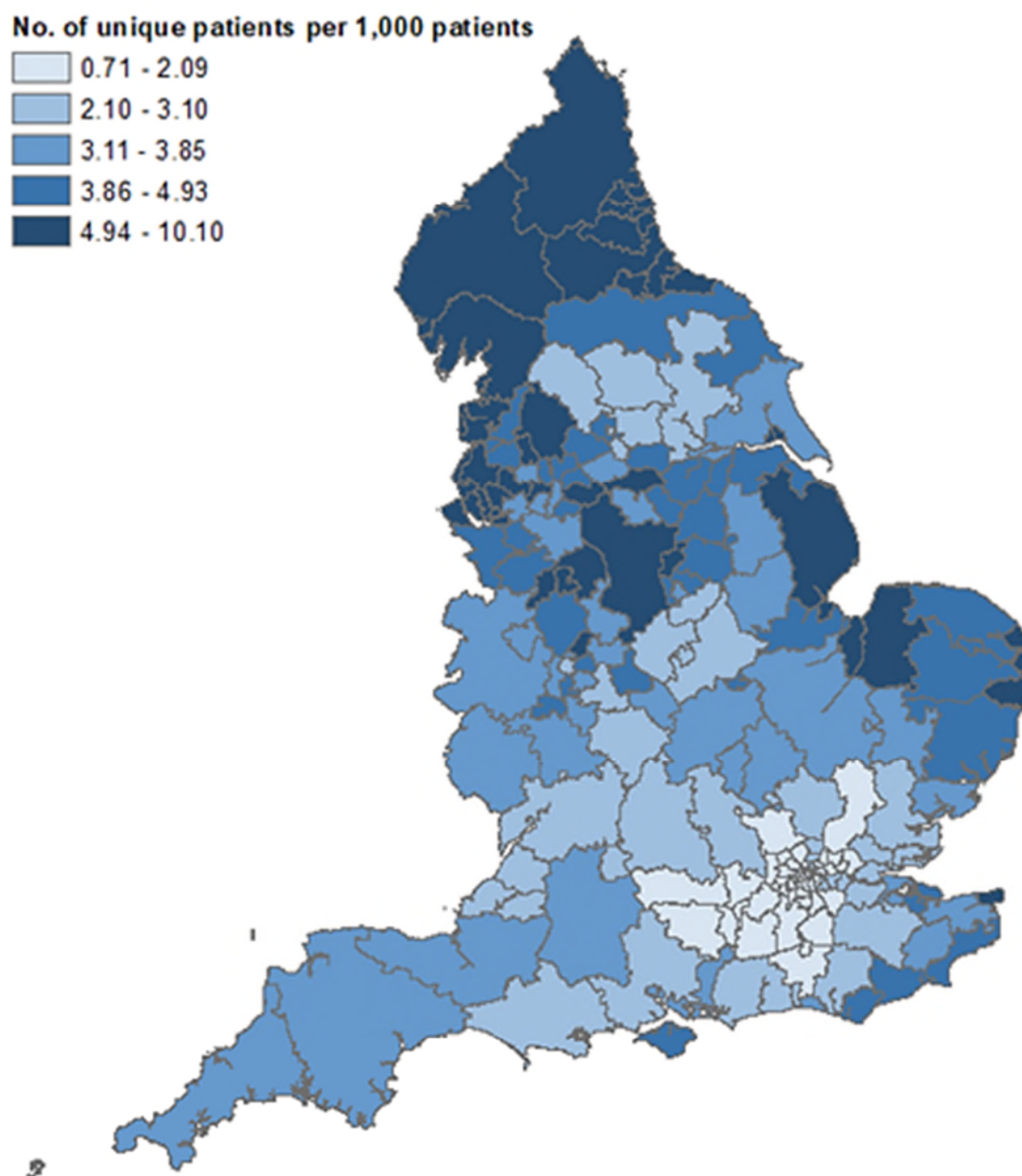
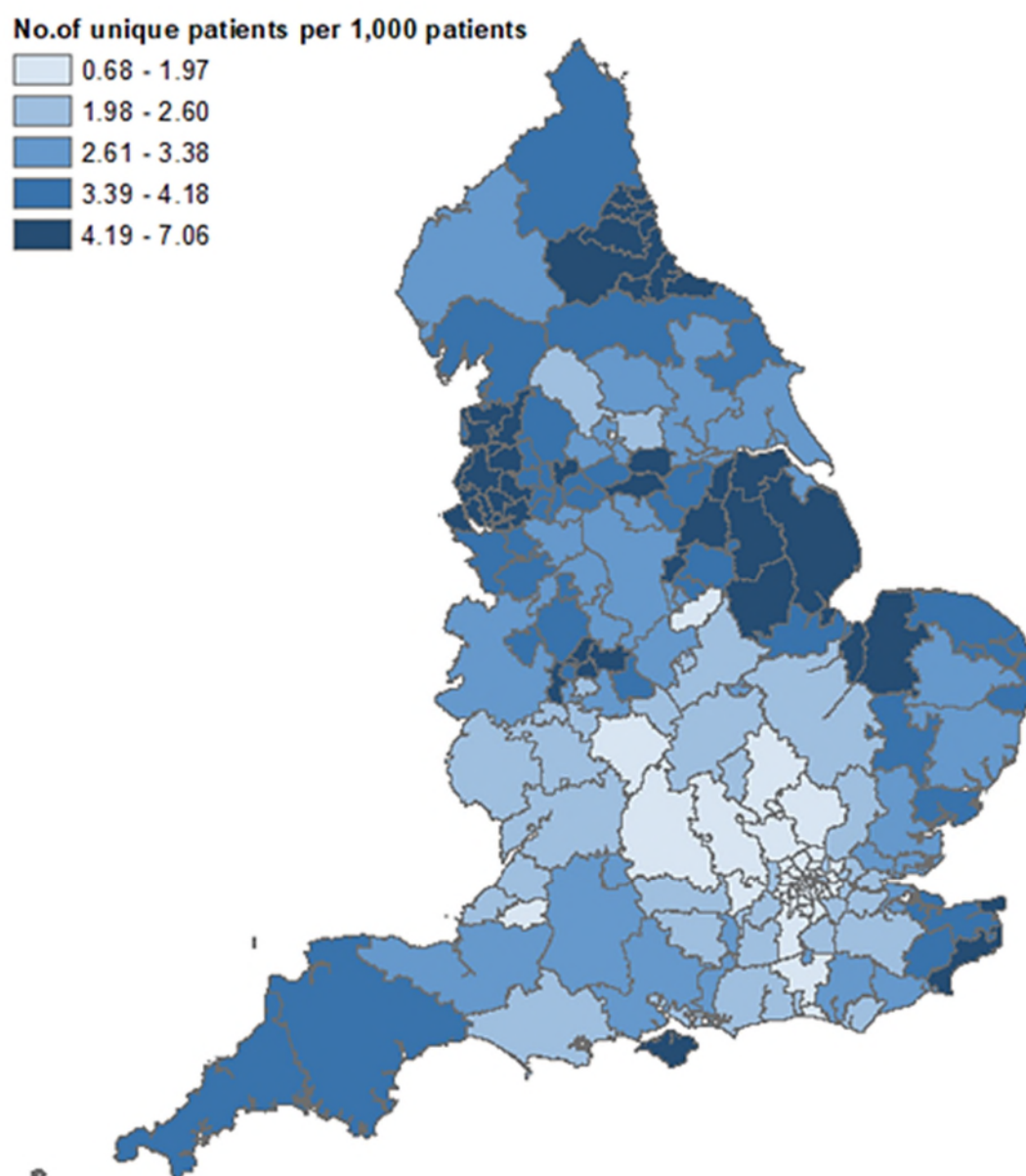


Figure 18: Prescribing of pregabalin and an opioid concurrently in 2019, numbers of unique patients per 1,000 patients by CCG

Prescribing by CCGs in 2019 is similar to those reported in 2018, with higher concurrent prescribing in the north and east of the country.



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